JACC Vol. 29, No. 5
April 1997:934–40

Bailout and Corrective Use of Gianturco-Roubin Flex Stents After Percutaneous Transluminal Coronary Angioplasty

Operator Reports and Angiographic Core Laboratory Verification From the National Heart, Lung, and Blood Institute/New Approaches to Coronary Intervention Registry

LARRY S. DEAN, MD, FACC, CHARLES J. GEORGE, MS,* GARY S. ROUBIN, MD, FACC, ELIZABETH D. KENNARD, PHD,* DAVID R. HOLMES, JR., MD, FACC,† SPENCER B. KING III, MD, FACC,‡ RONALD E. VLIETSTRA, MD,§ JEFFERY W. MOSES, MD, FACC,‖ DEAN KEREIAKES, MD, FACC,¶ JOSEPH P. CARROZZA, JR., MD, FACC,# STEPHEN G. ELLIS, MD, FACC,** JAMES R. MARGOLIS, MD, FACC,†† KATHERINE M. DETRE, MD, DRPH, FACC

Birmingham, Alabama; Pittsburgh, Pennsylvania; Rochester, Minnesota; Atlanta, Georgia; Lakeland and Miami Beach, Florida; New York, New York; Cincinnati, Ohio; Boston, Massachusetts; and Cleveland, Ohio

Objectives. **We sought to determine the in-hospital clinical outcome and angiographic results of patients prospectively entered into the National Heart, Lung, and Blood Institute/New Approaches to Coronary Intervention (NHLBI/NACI) Registry who received Gianturco-Roubin stents as an unplanned new device.**

Background. **Between August 1990 and March 1994, nine centers implanted Gianturco-Roubin flex stents as an unplanned new device in the initial treatment of 350 patients (389 lesions) who were prospectively enrolled in the NHLBI/NACI Registry.**

Methods. **Patients undergoing implantation of the Gianturco-Roubin flex stent were prospectively entered into the Gianturco-Roubin stent portion of the NHLBI/NACI Registry. Only subjects receiving the Gianturco-Roubin stent as a new device in an unplanned fashion are included.**

Results. **The mean age of the patient group was 61.8 years, and the majority of the patients were men. A history of percutaneous transluminal coronary angioplasty (PTCA) was present in 35.4% of the group, and 16.9% had previous coronary artery bypass graft surgery. Unstable angina was present in 67.7%. Double- or triple-vessel coronary artery disease was present in 55.4%, and the average ejection fraction was 58%. The presence of thrombus was noted in 7.3%, and 7.2% had moderate to severe tortuosity of the lesion. The angiographic success rate was 92%. Individual clinical sites reported that 66.3% of the stents were placed after suboptimal PTCA, 20.3% for abrupt closure and 13.4% for some other technical PTCA failure. Major in-hospital events occurred in 9.7% of patients, including death in 1.7%, Q wave myocardial infarction in 3.1% and emergency bypass surgery in 6%. Abrupt closure of a stented segment occurred in 3.1% of patients at a mean of 3.9 days. Cerebrovascular accident occurred in 0.3%, and transfusion was required in 10.6%. Vascular events with surgical repair occurred in 8.6% of patients.**

Conclusions. **Despite these complications, the use of this device for the treatment of a failed or suboptimal PTCA result remains promising given the adverse outcome of abrupt closure with conventional (nonstent) treatment.**

(J Am Coll Cardiol 1997;29:934–40)

Since the original description by Gruentzig et al. (1) of percutaneous transluminal coronary angioplasty (PTCA), a plethora of new coronary devices have been introduced to offset the drawbacks of PTCA. However, indications for use, risks and long-term efficacy of individual devices in the treatment of coronary artery disease remain to be completely defined. With this in mind, on November 1, 1990, the National Heart, Lung, and Blood Institute (NHLBI) implemented the New Approaches to Coronary Intervention (NACI) Registry (2). This manuscript describes the initial experience and in-hospital outcome in patients receiving the Gianturco-Roubin flex stent (Cook Inc.) who participated in the NACI Registry.

From the Department of Medicine, University of Alabama at Birmingham, Birmingham, Alabama; *Department of Epidemiology, University of Pittsburgh, Pittsburgh, Pennsylvania; †Adult Cardiology Department, Mayo Clinic, Rochester, Minnesota; ‡Emory University Hospital, Atlanta, Georgia; §Watson Clinic, Lakeland, Florida; ‖Lenox Hill Hospital, New York, New York; ¶The Christ Hospital, Cincinnati, Ohio; #Beth Israel Hospital, Boston, Massachusetts; **Cleveland Clinic Foundation, Cleveland, Ohio; and ††Miami Heart Institute, Miami Beach, Florida. This study was presented in part at the 65th Scientific Sessions of the American Heart Association, New Orleans, Louisiana, November 1992, and was supported by Grant 2-R01-HL44284-04A1 from the National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, Maryland.

Manuscript received August 17, 1995; revised manuscript received November 8, 1996, accepted December 20, 1996.

Address for correspondence: Dr. Larry S. Dean, 373 BDB, UAB Station, Birmingham, Alabama 35294-0012. E-mail: ldean@uab.edu.

0735-1097/97/$17.00
PII S0735-1097(97)00013-2

Abbreviations and Acronyms

E-CABG = emergency coronary artery bypass graft surgery
GRS = Gianturco-Roubin stent
NACI = New Approaches to Coronary Intervention
NHLBI = National Heart, Lung, and Blood Institute
PTCA = percutaneous transluminal coronary angioplasty
QMI = Q wave myocardial infarction
TIMI = Thrombolysis in Myocardial Infarction

Gianturco-Roubin stent (GRS) placement routinely follows either rescue for failed PTCA (manifested by early closure) or suboptimal PTCA (as determined by the individual practitioner, but typically based on some notion of "threatened closure"). This report describes the use of GRS in the patients enrolled in NACI and compares patients and lesions in which the stent was used as a bail-out for abrupt closure or other immediate complications after PTCA versus those in which the mode for use was "corrective" after a suboptimal PTCA result.

Methods

Data collection. Forty-one sites in North America participated in the Registry. Consecutive patients undergoing percutaneous intervention at a Registry site were included. All patients gave written informed consent to participate in the NACI Registry, and the individual sites had the approval of their Institutional Review Board before establishment of the Registry. In-hospital data including demographics, clinical history, operator-assessed angiographic or fluoroscopic variables, the nature of the procedure and outcomes were collected from each patient. Standard forms (2) were used and sent to the coordinating center at the University of Pittsburgh, where they were checked for validity and consistency. Resolution of any discrepancies was coordinated between the data collection center and the individual site, and all data were then entered into a data base. The angiographic recording of each procedure, whether successful or unsuccessful, was sent to a central angiographic core laboratory (Washington Heart Center). The films were then independently assessed using computerized edge detection algorithms. In addition, other lesion-specific morphologic characteristics were determined.

Subjects. From the Registry data base, we selected records from subjects who received a GRS. To analyze the effect of GRS without confounding by the concurrent use of other devices, we excluded subjects who also received treatment with other new devices. The adjunctive use of other new devices after GRS occurred rarely in the Registry. Only two patients who received Wiktor stents after GRS were excluded from the analysis. Because this stent is used primarily as an unplanned device and only 61 patients were registered as planned GRS recipients, we have only included subjects who received a GRS as an unplanned device during the procedure. However, we report on all attempts to use the GRS for this indication. A patient was entered into the Registry when the stent package was opened. Between August 1990 and August 1994, baseline NACI Registry data from 4,421 patients were verified and entered into the data base. Of these, 350 patients (389 lesions) at the nine GRS sites met the criteria. According to the site reports, 66.7% of the stent placements were for the treatment of suboptimal results with previous PTCA. The bail-out indication accounted for 33.3% of GRS use (20.1% for abrupt closure and 13.2% for some other PTCA technical failure). Sites were not held to a specific angiographic definition when reporting the mode for stent use.

End points. The procedure was considered to be successful if reduction of the target lesion (without emergency bypass surgery, myocardial infarction or death) was by at least 20% with <50% final diameter stenosis by core angiographic laboratory assessment. The major clinical end point was in-hospital death, myocardial infarction and bypass surgery. We monitored other complications such as abrupt stent closure (i.e., any in-hospital repeat revascularization of the treated vessel), coronary dissection, perforation and major bleeding.

Analysis. We categorized lesions into two groups: those in which GRS was a "bailout" device (i.e., site reported placement owing to abrupt closure or some other previous PTCA failure) versus "corrective" device (i.e., site reported mode for use was "suboptimal PTCA"). Six patients who had lesions treated for both reasons were placed in the bailout category. We employed logistic regression analysis to identify any variables likely to discriminate between the two groups. Any trendworthy variables ($p < 0.10$) were then entered simultaneously in a multiple logistic regression model, and a backward selection procedure was used to eliminate all but those factors which independently discriminated between the two groups with statistical significance ($p < 0.05$). We then employed multiple logistic regression analysis to identify which factors (including bailout vs. "corrective" use) were independently associated with major in-hospital complications. Angiographic variables are only reported from those patients with core laboratory data.

Results

Patient-specific characteristics. Both the bailout group and "corrective" group had similar clinical history profiles (Table 1). Patients were predominately (60.9%) men with a mean age of 61.8 years. Of the patients 35.4% had previous PTCA at a median time of 4.6 months earlier. A history of previous myocardial infarction was present in 52%, 30.3% within 6 weeks of the procedure. Angina was the primary reason for revascularization in 85.2% of the subjects, and in 67.7% it was unstable. Only 44% of the patients had single-vessel disease; 24.1% had three-vessel disease. The average ejection fraction was 58%. The average length of hospital stay was 9.26 days. No patient-specific characteristics showed any statistically significant difference between the groups.

Lesion-specific characteristics. Of the 389 lesions in this report, 361 (92.8%) underwent core laboratory assessment (Table 2). The site reported readings on the subset closely

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Table 1. Patient Characteristics

	Mode for Stent Use		
	All Subjects (n = 350)	Rescue (n = 118)	Corrective (n = 232)
Mean age (yr)	61.8	60.6	62.4
Male	60.9	62.7	59.9
Prior PTCA	35.4	34.7	35.8
Prior CABG	16.9	18.6	15.9
History of			
MI	52.0	55.1	50.4
CHF	8.3	8.0	8.4
Diabetes	16.4	17.9	15.6
Hypertension	51.1	53.0	50.2
CAD	39.4	42.6	37.6
Hypercholesterolemia	49.3	45.7	51.3
Never smoked	38.9	34.7	40.9
Unstable angina	67.7	66.1	68.5
MI within 6 wk	30.3	30.5	30.2
No. diseased vessels			
1	44.0	45.3	43.3
2	31.3	34.2	29.9
3	24.1	20.5	26.0
Mean LVEF (%)	58.0	56.1	59.1
No. of patients	193	68	125

Data presented are percent of patients, unless otherwise indicated. CABG = coronary artery bypass graft surgery; CAD = coronary artery disease; CHF = congestive heart failure; LVEF = left ventricular ejection fraction; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty.

parallels those of the full study, indicating that there was no appreciable selection bias with respect to the films being sent. Of stented vessels 42.6% were in the right coronary artery, 32.6% in the left anterior descending coronary artery, 18.1% in the left circumflex artery, 3.9% in a bypass graft and 0.8% in the protected left main coronary artery. Angiographic evidence of thrombus was present in 7.3%, and 21.9% had angiographic evidence of calcium. Of the lesions 23.4% represented restenoses. The mean reference vessel diameter was 3.04 mm, with a minimal lumen diameter of 0.80 mm (73.5% stenosis) before the procedure. The lesions averaged 12.80 mm in length, and 28.8% were ≥15 mm in length. The rescue group was distinguished by more total occlusions (17.1% vs. 3.2%, $p < 0.01$), worse Thrombolysis in Myocardial Infarction (TIMI) flow grade (28.8% vs. 7.5%, 0 or 1, $p < 0.01$) and more severe dissection (17.0% vs. 5.1%, grade F, $p < 0.01$) before stenting. There was no significant difference between the groups in any procedural angiographic characteristics, and stenting resulted in angiographic success in 92% of the treated segments.

Stent size and length. The most commonly used stent size was 3 mm, and the majority of patients (76%) had a ≥3-mm stent placed. The use of the 2-mm diameter stent is decidedly rare (0.3%) in the Registry, probably representing concerns over abrupt closure and the risk/benefit ratio with regard to the requirements for anticoagulation after stent placement. Although stents both 12 and 20 mm in length were available during Registry enrollment, the majority of patients had the 20-mm length stent placed (61.6% had 20 mm and 38.4% had 12 mm).

The most frequent device complication was failure to cross the lesion with the device in 3.9%, which was equally common in both groups (3.8% in bail-out group vs. 3.9% in corrective group). The stent was withdrawn in 3.3% of the lesions attempted.

Major in-hospital events. Table 3 shows that death, Q wave myocardial infarction (QMI) and emergency coronary artery bypass graft surgery (E-CABG) were twice as prevalent in the bailout group. Except for QMI, the difference in rates was statistically significant ($p < 0.01$). The overall in-hospital mortality rate was 1.7%, with a QMI rate of 3.1% and an E-CABG rate of 6%. Death, QMI or E-CABG, or a combination of these, occurred in 9.7% overall. Abrupt vessel closure occurred within the first 24 h after the procedure in 0.6%, with a cumulative in-hospital occurrence rate of 3.1% (mean 3.9 days, range 0 to 5 after stenting). Hemorrhage requiring transfusion occurred in 10.6%, and vascular events requiring surgical treatment occurred in 8.6%. There was no difference between the bailout and corrective groups. Clinical evidence of cerebrovascular accident in the hospital occurred in 0.3%.

Table 4 shows the logistic regression estimates of significant patient and lesion characteristic effects on major in-hospital complications (death, E-CABG or QMI). Because the bailout group clearly had a distinctly elevated rate, that factor was forced into every model. Adjusting only for bailout use, a number of factors were significant, especially recent myocardial infarction, multivessel disease, severe dissections and poor TIMI flow before stenting and smaller lumen diameter after the procedure. A final multiple logistic regression model is presented in Figure 1. This shows that major complications were more common in patients with a recent myocardial infarction, multivessel disease, tortuous lesions and at least one attempted lesion with >40% postresidual stenosis. The reduced sample size (290 patients with complete data) and the low number of events (24 events) limit the power to rule out other potential predictors of complications. Therefore, caution should be used in the interpretation of these results.

After a similar analysis of factors associated with repeat revascularization (CABG or target PTCA) within 10 days after the stent attempt, a number of significant clinical and angiographic factors were identified. Patients with high residual stenoses or residual thrombi are more likely to need reintervention. As with in-hospital complications, this analysis is limited by the low event rate and the number of cases with complete data (27 events in 253 patients).

Discussion

We report the initial experience and in-hospital outcome in a diverse group of patients receiving the GRS for bailout or corrective use at nine different institutions involved in the NHLBI/NACI Registry. This Registry represents a unique data set in that it was prospectively collected, monitored for accuracy by the data coordinating center and had core labora-

Table 2. Lesion Characteristics

	All Subjects	Rescue	Corrective
No. of leions	389	131	258
No. with core laboratory reading	369	122	247
Restenotic lesion	23.4%	16.2%	26.7%*
Location			
RCA	42.6%	47.0%	40.5%
LAD	32.6%	32.5%	32.6%
LCx	18.1%	13.7%	20.2%
CABG	3.9%	2.6%	4.5%
LMCA	0.8%	0.9%	0.8%
Thrombus	7.3%	10.2%	6.0%
Tortuosity			
Severe	1.7%	3.7%	0.9%
Moderate	5.5%	7.4%	4.7%
None	92.7%	88.9%	94.5%
Eccentricity	37.0%	37.0%	37.0%
Calcium	21.9%	11.1%	21.3%
Ulcerated	12.3%	12.5%	12.9%
Mean lesion length (mm)	12.80	11.84	13.21
Ref vessel size (mm)	3.04	3.08	3.03
Before PTCA			
MLD (mm)	0.80	0.83	0.79
% stenosis	73.5%	72.1%	74.1%
Total occlusion	19.3%	21.8%	17.0%
TIMI flow grade			
0	16.3%	18.5%	15.3%
1	5.5%	4.6%	6.0%
2	8.2%	7.4%	8.5%
3	70.0%	69.4%	70.2%
ACC/AHA dissection grade			
A	0.3%	0.0%	0.4%
B	0.9%	0.9%	0.9%
C	2.3%	2.8%	2.1%
D	5.0%	5.6%	4.7%
E	1.5%	1.9%	1.3%
F	1.7%	3.7%	0.9%
Before stent			
MLD (mm)	1.47	1.12	1.50
% stenosis	51.23%	63.3%	49.5%
Total occlusion	7.7%	17.1%	3.2%†
TIMI flow grade			†
0	5.8%	12.8%	2.8%
1	8.1%	16.0%	4.7%
2	7.8%	7.4%	7.9%
3	78.3%	63.8%	84.7%
ACC/AHA dissection grade			†
A	2.9%	2.1%	3.3%
B	13.6%	4.3%	17.7%
C	23.6%	18.1%	26.0%
D	25.2%	14.9%	29.8%
E	5.8%	7.4%	5.1%
F	8.7%	17.0%	5.1%
After procedure			
MLD (mm)	2.38	2.44	2.35
% stenosis	22.40%	22.67%	22.28%
Total occlusion	0.0%	0.0%	0.0%
TIMI flow grade			
0	0.0%	0.0%	0.0%
1	0.9%	2.0%	0.4%
2	0.9%	0.0%	1.3%
3	98.2%	98.0%	98.2%
ACC/AHA dissection grade			
A	8.3%	7.1%	8.8%
B	12.0%	10.1%	12.8%
C	11.1%	10.1%	11.5%
D	8.3%	12.1%	6.6%
E	0.9%	1.0%	0.9%
F	0.3%	0.0%	0.4%
Angiographic lesion success			
Change >20% and residual stenosis <50%	92.0%	90.8%	92.4%
TIMI flow grade 3 and residual stenosis <50%	93.5%	93.9%	93.3%
Residual stenosis <50%	94.4%	94.9%	94.2%

*p < 0.05. †p < 0.01. ACC/AHA = American College of Cardiology/American Heart Association; CABG = coronary artery bypass graft surgery; LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; LMCA = left main coronary artery; MLD = minimal lumen diameter; PTCA = percutaneous transluminal coronary angioplasty; RCA = right coronary artery; Ref = reference; TIMI = Thrombolysis in Myocardial Infarction trial.

tory quantification and verification of angiographic results. It is the only report of the use of this device with independent angiographic core laboratory verification of the angiographic results. It reports the results of all patients undergoing GRS implantation in an unplanned fashion, including those with unsuccessful GRS deployment. This report should serve as a new benchmark to compare similar devices (i.e., other stents) or techniques (e.g., prolonged balloon inflation) for the indications presented.

Coronary angioplasty and abrupt closure. Although there have been substantial improvements in PTCA balloon, guiding catheter and guide wire technology, abrupt closure continues to occur in ~2% to 10% (3,4), or higher (5), of patients undergoing interventional procedures. The incidence of abrupt closure appears to be a constant potential complication with angioplasty, as a comparison of the NHLBI/PTCA Registry (6,7) results shows that despite a more complex patient subset

Table 3. Rates of Major In-Hospital Complications

	All Subjects (n = 350)	Rescue (n = 118)	Corrective (n = 232)
Death	1.7%	4.2%	0.4%*
Emergency CABG	6.0%	11.0%	3.4%†
Any CABG	8.6%	15.3%	5.2%†
Any MI	12.0%	17.8%	9.1%*
Q wave MI	3.1%	3.4%	3.0%
Death/CABG/Q wave MI	9.7%	16.1%	6.5%†
Any complication (death/CABG/MI)	19.1%	30.5%	13.4%†
Procedural success	85.1%	80.5%	87.1%
No. of patients	288	87	201

*p < 0.05. †p < 0.01. Abbreviations as in Table 1.

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Table 4. Logistic Regression Analysis of Core Laboratory Factors Associated With Major Complications (death, Q wave myocardial infarction or emergency coronary artery bypass graft surgery): Odds Ratio (95% confidence interval)

	Adjusted Only for Rescue ($p < 0.10$)	Adjusted for All Factors ($p < 0.05$) and Bailout ($n = 290$, 24 events)
Bailout use	2.78 (1.36–5.69)	2.34 (0.89–6.12)
MI in past 6 wk	2.99 (1.44–6.20)	4.77 (1.83–12.47)
Multivessel disease	2.50 (1.12–5.57)	4.03 (1.27–12.73)
Before procedure		
LAD lesions	0.42 (0.18–1.01)	
LCx lesions	0.30 (0.08–1.04)	
CABG lesions	0.48 (0.06–3.99)	
LMCA lesions	2.10 (0.17–25.65)	
Class B2 or C lesions	7.64 (1.78–32.83)	
Tortuous lesions	3.27 (1.15–9.30)	3.33 (0.83–13.43)
Before stent		
Abrupt closure	3.08 (1.25–7.73)	
Grade D dissections	0.67 (0.21–2.13)	
Grade E dissections	1.31 (0.27–6.39)	
Grade F dissections	3.43 (1.20–9.83)	
TIMI flow grade 0 lesions	2.00 (0.50–8.06)	
TIMI flow grade 1 lesions	3.56 (1.18–0.48)	
TIMI flow grade 2 lesions	1.81 (0.48–6.84)	
After procedure		
MLD <2 mm	2.85 (1.19–6.82)	
20–40% diameter stenoses	1.34 (0.47–3.83)	1.04 (0.34–3.18)
40–100% diameter stenoses	7.80 (2.61–23.36)	6.27 (1.94–20.28)
TIMI flow grade 0 lesions	NA	
TIMI flow grade 1 lesions	4.72 (0.39–56.47)	
TIMI flow grade 2 lesions	8.00 (0.68–94.59)	
Lesions with thrombus	2.80 (0.84–9.35)	

Because patients may have multiple lesions, categories of angiographic risk factors are not mutually exclusive. Patients with missing core laboratory readings were excluded. NA = not applicable; other abbreviations as in Tables 1 and 2.

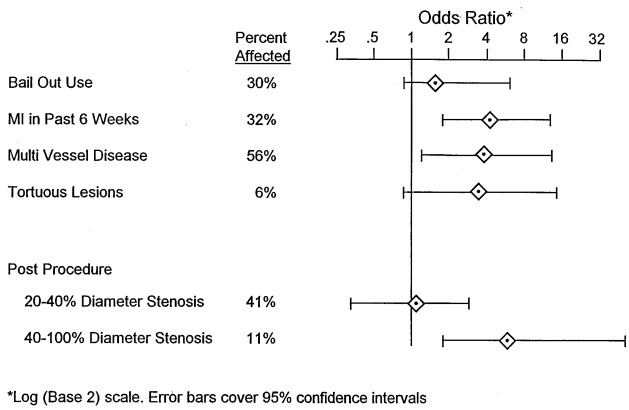

Figure 1. Multiple logistic regression model of site and core laboratory factors associated with major in-hospital complications (249 lesions, 290 patients, 24 events). MI = myocardial infarction.

in the 1985 to 1986 registry, the incidence of abrupt closure was similar to the earlier registry. Newer devices including rotational and directional atherectomy (8,9), laser angioplasty (10) and perfusion balloon technology (11) have not yielded consistent results in reducing the rate of abrupt closure or its treatment.

The GRS appears to be effective in stabilizing the lumen of a coronary vessel after complicated angioplasty (12). It also appears to decrease the rate of subsequent QMI, emergency or in-hospital CABG and perhaps mortality compared with historic controls. Because the Registry is not a randomized trial to compare the efficacy of the GRS to that of conventional angioplasty, the results must therefore be compared to other retrospective and prospective nonrandomized PTCA trials, which can serve as historic controls.

Effect of stenting on abrupt or threatened closure. In the initial experience with balloon angioplasty, failure of the technique was associated with the need for E-CABG in the majority of patients. Emergency CABG is associated with increased morbidity and mortality after failed angioplasty. The incidence of QMI ranges from 11% to 61% in the published data (13,14). It also appears that the incidence of death after E-CABG for failed angioplasty is also increased, ranging from no deaths reported in some series to 12% or higher (15–17). In addition, as reported in the 1985 to 1986 NHLBI/PTCA Registry (7), the occurrence of abrupt vessel closure complicating PTCA was not only associated with a higher in-hospital mortality and morbidity, but also with a higher incidence of myocardial infarction and death in the 18 months after the procedure. Clearly, abrupt closure after PTCA is not a benign event in the hospital or in follow up.

The concept of threatened closure after PTCA is somewhat more problematic because there is no unifying definition of the event. Attempts have been made to define the process of threatened closure, with Roubin et al. (18) defining threatened closure as having one or more of the following: ≥50% residual stenosis after PTCA, dissection ≥15 mm in length, TIMI flow grade 2 (19) after PTCA and ongoing myocardial ischemia manifested by continued chest pain, persistent electrocardiographic changes consistent with ischemia, cardiac arrhythmias or hemodynamic instability. In a more recent report Ferguson et al. (20) attempted to risk-stratify patients with suboptimal angioplasty results into subgroups that are likely to have a poor clinical outcome. Despite attempts at defining threatened closure more clearly, it nonetheless continues to be somewhat imprecise and in all likelihood will never be defined to the degree of abrupt closure. However, a suboptimal angioplasty result or threatened closure is clearly associated with a poorer outcome in the hospital and in follow up (21,22). In this report, a severe dissection after PTCA, independent of total occlusion and postprocedural stenosis, shows a trend toward predicting major in-hospital complications.

In the treatment of abrupt or threatened closure, which represented most of the patients in this report, the incidence of death was 1.7%, QMI 3.1% and E-CABG 6%. These data compare favorably with the previously published historic data as discussed. The use of historic controls requires us to assume that bail-out cases from earlier years would be comparable to the cases selected for bail-out stenting in more recent series, whereas nonrandom effects such as evolving patient selection

remain uncontrolled. In contrast, the NHLBI/PTCA and NHLBI/NACI registries provide us with heterogeneous pools of cases that are uniformly collected from multiple centers, and probably offer the closest approximation to a "real world comparison."

There are several modes of GRS use observed by NACI that are beyond the scope of this report. A cohort of 77 patients who had GRS implantation in conjunction with another new device was excluded from this report. To our knowledge, no data have been published that address the performance of GRS as a bail-out for atherectomy, other stents or lasers. A detailed report comparing these circumstances with the unplanned use after PTCA described in this report will greatly enhance our understanding of unplanned stenting.

Complications of stenting. This stent, as well as others (23,24), requires meticulous attention to detail regarding implantation, anticoagulation and nursing care. As demonstrated by George et al. (25), in their review of the Cook registry data, there is a definite learning curve regarding the need for blood transfusion and vascular surgical repair of groin complications. This is probably due to improved operator and ancillary personnel experience in the management of these patients after stent placement. Overanticoagulation definitely impacts both morbidity and mortality after stent placement.

The need for anticoagulation is directed toward the concern over abrupt closure after stent placement. Liu et al. (26) reported by multivariate analysis that three factors increase the likelihood of abrupt stent thrombosis with this device: a stent <3 mm in diameter, a residual filling defect or a residual dissection after stent deployment. The incidence of stent thrombosis in a group of patients having the device placed for abrupt or threatened closure was 1% in patients who had none of the above risk factors, 8% in those with one risk factor and 28% in those with two or more risk factors. In the NACI Registry, 24% of the stents placed were <3 mm in size, 32.6% of the stents placed had some dissection (grades B to F) present after stenting and 6.2% had evidence of residual thrombus. In addition, the minimal lumen diameter of 2.38 mm after stent placement suggests incomplete stent expansion. The routine use of high pressure balloon inflation after stent placement to ensure complete stent expansion was not done in the Registry. A recent report (27) suggests that this may impact both the initial angiographic result, abrupt stent closure and restenosis rates in follow-up. The incidence of abrupt closure after placement of the GRS in the NACI Registry is similar to that seen in previous reports with this device using a similar implantation technique (25). A recent report from Europe with this stent (28) and another report (29) suggest that for de novo and bail-out indications in large vessels, anticoagulation can be markedly reduced and in some cases eliminated entirely. Appropriate patient selection for intracoronary stenting will continue to impact the abrupt and long-term complications of the procedure.

Conclusions. Despite the limitations of this device, it appears to have great promise in the treatment of abrupt or threatened closure after PTCA. It will no doubt have a profound impact on the selection of patients undergoing PTCA, potentially allowing for more complex clinical and lesion subsets, thus expanding the horizons of patients undergoing PTCA. It will likewise have an impact on health care expenditure by allowing patients with a "bail-out" procedure to avoid the morbidity, mortality and increased cost of undergoing E-CABG after failed angioplasty (30). It is premature, however, to suggest that surgical standby for PTCA and the performance of PTCA in hospitals without on-site access to cardiovascular surgery be endorsed.

Caution should be exercised in appropriate patient selection, and meticulous attention to poststent management. Hopefully, with new developments in stent technology, as have occurred in balloon angioplasty, devices will become more easily placed and require less aggressive or no anticoagulation after placement. These potential improvements will greatly impact the morbidity and mortality connected with stenting for abrupt or threatened closure after PTCA.

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